

**REMARKS**

As noted previously, patents corresponding generally to the instant application have been challenged overseas. An oral hearing on the oppositions were held last week. Review has indicated that a number of documents have been advanced against the corresponding European patents in the oppositions beyond those already of record by means of an IDS or by citation by the Examiner. Therefore, a new IDS is being filed simultaneously with this response.

The documents being simultaneously submitted are designated in the upper right hand corner by a document number proceeded either by the letter A or the letter C. The attempted logic in this numbering system is that the A documents relate to assertions of insufficiency or background information while the C documents are those which are or might be relevant for consideration of prior art.

While all documents submitted in connection with the European oppositions have been numbered, not all of these documents are being submitted. For example, one series (documents numbered C9-C19 and C31a to C31e) relate to assertions of prior use in Europe and hence are not relevant here. Virtually all of the "A" documents are evidence after the priority date to which this application is entitled. Accordingly, only two A documents are being submitted. Both were submitted by the inventors' assignee and are public record in the oppositions. A39 is a summary of arguments for patentability and A43 is predominantly a response to assertions of insufficiency of disclosure. Both A39 and A43 internally refer to materials on which the opponents relied and which may not have been submitted here. The Examiner is respectfully requested to consider whether he wishes to see that material. If so, they will be provided (with translation into English where available) on request.

With respect to the documents now being submitted, the following additional comments are believed to be appropriate. The present applicants' assignee told the EPO Opposition examiners that C38 was non-enabling because there is a fundamental

disagreement between the analysis of the starting raw material and the analysis of fiber which is made solely from the starting raw material and therefore should have the same analysis. C38c is a calculation showing that fibre 1 (the only fibre on which the opponents relied) started from  $\text{SiO}_2:\text{Al}_2\text{O}_3:\text{CaO}$  in a ratio of 42.7:16.9:11.5 and by only melting, obtained a ratio of 40.8:18.1:16.2. The undersigned has been advised that the EPO Opposition examiners ruled that C38 was non-enabling for fibre 1. Document C26 is a disclosure of manufacturing compositions solely from analytically pure starting materials and so their resulting melt will not contain titania and C48 is a subsequent document by the same authors. While it has been asserted by the opponents in Europe that C48 was open to public inspection (see C48a), an independent technical library, the Technical Knowledge Center of Denmark, sent a letter to Glafo (the alleged publisher of C48) which in Danish asks for a copy of C48 and Glafo returned the letter with a manuscript note in both Swedish and Danish which in translation says "this report is not open to public inspection material". A copy of this letter is attached to this response.

While all of the foregoing is believed to be accurate, the Examiner is respectfully requested to make an independent evaluation of all submitted material and statements.

In light of the previously issued patents to the applicants' assignee, it has been decided to further revise the claims in this application. All of the revisions, as well as new claims, find basis in the claims pending before the current amendment, with further attention being given to the rejection under §112. Some grammatical changes have also been made.

With respect to the §112 rejection, the typographical error noted by the Examiner has been corrected and since the other change in the claim made claim 30 identical to claim 38, claim 38 and the claims made redundant as a result thereof have been cancelled. In claim 43, "the" lung and environment has been changed to "a" lung and "an" environment, and a similar change has been made in claim 46 as well as adopting the Examiners helpful suggestion. Claim 52 has been amended in the same manner as claim 43. It is respectfully submitted that the amendment to the amount of alumina in claim 58

has eliminated the rejection of this claim and the reference to the maximum amount of FeO is not a redundancy because of the word "below". In light of these changes, withdrawal of the rejection to §112, second paragraph, is respectfully requested.

Claims 45 and 58 were rejected under 35 U.S.C. 112, first paragraph on the grounds that the application did not have support for the recited limitation. Applicants respectfully submit that there is such support and respectfully invite the Examiner's attention to page 15, last column and the tables on pages 22 and 23. Withdrawal of this rejection is respectfully solicited.

The pending claims are rejected under 35 U.S.C. § 102 or § 103 over Massol or Lakatos. These rejections are respectfully traversed.

It is respectfully submitted that the rejection based on §102 is not tenable. All of the independent claims in this case, in addition to the oxide concentration, contain a recitation of viscosity and/or dissolution rate. Neither of these references have any teachings with regard to the dissolution rate. Massol also has no teaching with regard to viscosity.

The present invention relates to man made vitreous fibers which are durable in use and which can be shown to be biologically advantageous. Because of a perceived health risk associated with the manufacture and use of such man made vitreous fibers, commercial interest led manufacturers to produce fibers which characteristics satisfy an *in vitro* test for the dissolution rate or degradability of the fibers. In this test, the fibers are placed in a liquid intended to simulate lung liquid (such as Gamble's solution) which has pH of 7.5. A consequence of this enhanced dissolution rate at pH 7.5 is that the fibers normally have a reduced resistance to humidity. A characteristic of many fibers which are alleged to have such an enhanced dissolution rate in such *in vitro* tests is that the fibers have a reduced aluminum content generally below 4%. However, a problem with many of these fibers is that the melt properties are not satisfactory for manufacture in conventional or easily adapted melting and fiber forming apparatus.


The present invention is based, *inter alia*, on the realization that macrophages which attack foreign bodies in the lung and which generate a pH around 4.5 are more important.

In order to realize a present invention, one skilled in the art will have to do all of the following. First, a composition will have to be prepared by first selecting amount of  $\text{SiO}_2$  in the range of 32 to below 45%, and then an amount of  $\text{Al}_2\text{O}_3$  in the range of above 16 to 28% must be selected, and then an amount of CaO in the amount of 10 to 30% must be selected, and then an amount of MgO in the amount of 2-20% must be selected, and then a combination of sodium and potassium oxides in an amount of up to 12% must be selected, and then the amount of  $\text{TiO}_2$  in an amount of up to 4% must be selected, and then the presence of other materials must be restricted such as other elements are up to 8% and then each of these percentages must be adjusted such of the composition has a viscosity at 1400°C of 10 to 70 poise and, with respect to some claims, the fibers produced have a dissolution rate of at least 20 nm per day when measured at a pH 4.5. Why would one do so? What is there in either of these references, whether considered alone or in combination, which would motivate one skilled in the art to make all of these selections simultaneously? The number of selections which must be made and the total lack of guidance in the prior art makes the likelihood that the artisan would make the appropriate selections, even by serendipity, very remote.

In light of all of the foregoing considerations, it is respectfully submitted that this application is not in condition to be allowed and the early issuance of a Notice of Allowance is respectfully solicited.

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Respectfully submitted,

By 

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